

with respect to the debarment in accordance with procedures adopted by the Official State Agency. The Official State Agency shall thereupon decide whether the debarment order shall continue in effect. Such decision shall be final unless the debarred participant, within 30 days after the issuance of the debarment order, requests the Administrator to determine the eligibility of the debarred participant for participation in the Plan. In such event the Administrator shall determine the matter de novo in accordance with the rules of practice in 7 CFR part 50, which are hereby made applicable to proceedings before the Administrator under this section. The definitions in 7 CFR 50.10 and the following definitions shall apply with respect to terms used in such rules of practice:

(a) *Administrator* means the Administrator, Animal and Plant Health Inspection Service of the U.S. Department of Agriculture or any officer or employee to whom authority has heretofore been delegated or to whom authority may hereafter be delegated to act in his stead.

[36 FR 23112, Dec. 3, 1971, as amended at 38 FR 3038, Feb. 1, 1973. Redesignated at 44 FR 61586, Oct. 26, 1979, and amended at 47 FR 21991, May 20, 1982; 67 FR 8468, Feb. 25, 2002]

§ 145.14 Testing.

Poultry must be more than 4 months of age when tested for an official classification: *Provided*, That turkey candidates under subpart D of this part may be tested at more than 12 weeks of age; game bird candidates under subpart E of this part may be tested when more than 4 months of age or upon reaching sexual maturity, whichever comes first; and ostrich, emu, rhea, and cassowary candidates under subpart F of this part may be tested when more than 12 months of age. Samples for official tests shall be collected by an Authorized Agent, Authorized Testing Agent, or State Inspector and tested by an authorized laboratory, except that the stained antigen, rapid whole-blood test for pullorum-typhoid may be conducted by an Authorized Testing Agent or State Inspector. For Plan programs in which a representative sample may be tested in lieu of an entire flock, except the ostrich, emu, rhea, and casso-

wary program in §145.63(a), the minimum number tested shall be 30 birds per house, with at least 1 bird taken from each pen and unit in the house. The ratio of male to female birds in representative samples of birds from meat-type chicken, waterfowl, exhibition poultry, and game bird flocks must be the same as the ratio of male to female birds in the flock. In houses containing fewer than 30 birds other than ostriches, emus, rheas, and cassowaries, all birds in the house must be tested.

(a) *For Pullorum-Typhoid*. (1) The official blood tests for pullorum-typhoid shall be the standard tube agglutination test, the microagglutination test, the enzyme-linked immunosorbent assay test (ELISA), or the rapid serum test for all poultry; and the stained antigen, rapid whole-blood test for all poultry except turkeys. Official blood tests must be conducted in accordance with part 147 of this subchapter or according to literature provided by the producer. Only antigens approved by the Department and of the polyvalent type shall be used for the rapid whole-blood and tube agglutination tests. Each serial of tube antigen shall be submitted by the antigen producer to the Department for approval upon manufacture and once a year thereafter as long as antigen from that serial continues to be made available for use. All microtest antigens and enzyme-linked immunosorbent assay reagents shall also be approved by the Department.¹

(2) [Reserved]

(3) There shall be an interval of at least 21 days between any official blood test and any previous test with pullorum-typhoid antigen.

(4) [Reserved]

(5) The official blood test shall include the testing of a sample of blood from each bird in the flock: *Provided*, That under specified conditions (see applicable provisions of §§145.23, 145.33, 145.43, 145.53 and 145.63) the testing of a

¹The criteria and procedures for Department approval of antigens and reagents may be obtained from the Animal and Plant Health Inspection Service, Veterinary Services, Center for Veterinary Biologics, 510 South 17th Street, Suite 104, Ames, IA 50010-8197.

portion or sample of the birds may be used in lieu of testing each bird.

(6) Poultry from flocks undergoing qualification testing for participation in the Plan that have a positive reaction to an official blood test named in paragraph (a)(1) of this section shall be evaluated for pullorum-typhoid as follows:

(i) Serum samples that react on rapid serum test or enzyme-labeled immunosorbent assay test (ELISA), or blood from birds that react on the stained antigen, rapid whole-blood test for all birds except turkeys, shall be tested with either the standard tube agglutination test or the microagglutination test.

(ii) Reactors to the standard tube agglutination test (in dilutions of 1:50 or greater) or the microagglutination test (in dilutions of 1:40 or greater) shall be submitted to an authorized laboratory for bacteriological examination. If there are more than four reactors in a flock, a minimum of four reactors shall be submitted to the authorized laboratory; if the flock has four or fewer reactors, all of the reactors must be submitted. Bacteriological examination must be conducted in accordance with part 147 of this subchapter. When reactors are submitted to the authorized laboratory within 10 days of the date of reading an official blood test named in paragraph (a)(6)(i) of this section, and the bacteriological examination fails to demonstrate pullorum-typhoid infection, the Official State Agency shall presume that the flock has no pullorum-typhoid reactors.

(iii) If a flock owner does not wish to submit reactors for bacteriological examination, then the reactors shall be isolated and retested within 30 days using an official blood test named in paragraph (a)(1) of this section. If this retest is positive, additional examination of the reactors and flock will be performed in accordance with paragraph (a)(6)(ii) of this section. During this 30-day period, the flock must be maintained under a security system, specified or approved by the Official State Agency, that will prevent physical contact with other birds and assure that personnel, equipment, and supplies that could be a source of pullorum-typhoid spread are sanitized.

(7) When *S. pullorum* or *S. gallinarum* organisms are isolated by an authorized laboratory from baby poultry, or from fluff samples produced by hatching eggs, the infected flock shall qualify for participation in the Plan with two consecutive negative results to an official blood test named in paragraph (a)(1) of this section. A succeeding flock must be qualified for participation in the Plan's pullorum-typhoid program with a negative result to an official blood test named in paragraph (a)(1) of this section. Testing to qualify flocks for Plan participation must include the testing of all birds in infected flocks and succeeding flocks for a 12-month period, and shall be performed or physically supervised by a State Inspector; Provided, That at the discretion of the Official State Agency, a sample of at least 500 birds, rather than all birds in the flock, may be tested by the State Inspector if it is agreed upon by the Official State Agency, the flockowner, and the Administrator. If the State Inspector determines that a primary breeding flock has been exposed to *S. pullorum* or *S. gallinarum*,² the Official State Agency shall require:

(i) The taking of blood samples—performed by or in the presence of a State Inspector—from all birds on premises exposed to birds, equipment, supplies, or personnel from the primary breeding flock during the period when the State Inspector determined that exposure to *S. pullorum* or *S. gallinarum* occurred.²

(ii) The banding of all birds of these premises—performed or physically supervised by a State Inspector—in order to identify any bird that tests positive; and

(iii) The testing of blood samples at an authorized laboratory using an official blood test named in paragraph (a)(1) of this section.

(8) All domesticated fowl, except waterfowl, on the farm of the participant shall either be properly tested to meet

²In making determinations of exposure, the State Inspector shall evaluate both evidence proving that exposure occurred and circumstances indicating a high probability of contacts with: infected wild birds; contaminated feed or waste; or birds, equipment, supplies, or persons from or exposed to flocks infected with *S. pullorum* or *S. gallinarum*.

the same standards as the participating flock or these birds and their eggs shall be separated from the participating flock and its eggs.

(9) All tests for pullorum-typhoid in flocks participating in or candidates for participation in the Plan shall be reported to the Official State Agency within 10 days following the completion of such tests. All reactors shall be considered in determining the classification of the flock.

(10) Any drug, for which there is scientific evidence of masking the test reaction or hindering the bacteriological recovery of *Salmonella* organisms, shall not be fed or administered to poultry within 3 weeks prior to a test or bacteriological examination upon which a *Salmonella* classification is based.

(11) When suitable evidence, as determined by the Official State Agency or the State Animal Disease Control Official, indicates that baby or started poultry produced by participating hatcheries are infected with organisms for which the parent flock received an official control classification and this evidence indicates that the infection was transmitted from the parent flock, the Official State Agency may, at its discretion, require additional testing of the flock involved. If infection is found in the parent flock, its classification shall be suspended until the flock is requalified under the requirements for the classification. Furthermore, the Official State Agency may require that the hatching eggs from such flocks be removed from the incubator and destroyed prior to hatching. When *Salmonella* organisms are isolated from a specimen which originated in a participating hatchery, the Official State Agency shall attempt to locate the source of the infection. The results of the investigation and the action taken to eliminate the infection shall be reported by the Official State Agency to the Service.

(b) For *Mycoplasma gallisepticum*, *M. meleagridis*, and *M. synoviae*. (1) The official tests for *M. gallisepticum*, *M. meleagridis*, and *M. synoviae* shall be the serum plate agglutination test, the tube agglutination test, the hemagglutination inhibition (HI) test, the microhemagglutination inhibition

test, the enzyme-linked immunosorbent assay (ELISA) test,³ a polymerase chain reaction (PCR)-based test, or a combination of two or more of these tests. The HI test or the microhemagglutination inhibition test shall be used to confirm the positive results of other serological tests. Tests must be conducted in accordance with this paragraph (b) and in accordance with part 147 of this subchapter. HI titers of 1:40 or more may be interpreted as suspicious, and final judgment must be based on further samplings and/or culture of reactors.

(2) The serological tests shall be conducted using *M. gallisepticum*, *M. meleagridis*, or *M. synoviae* antigens approved by the Department or the Official State Agency and shall be performed in accordance with the recommendations of the producer of the antigen.

(3) When reactors to the test for which the flock was tested are submitted to a laboratory as prescribed by the Official State Agency, the final status of the flock will be determined in accordance with part 147 of this subchapter.

(4) Any drug, for which there is scientific evidence of masking the test reaction or hindering the bacteriological recovery of mycoplasma organisms, shall not be fed or administered to poultry within three weeks prior to a test or bacteriological examination upon which a *Mycoplasma* classification is based.

³Procedures for the enzyme-linked immunosorbent assay (ELISA) test are set forth in the following publications:

A.A. Ansari, R.F. Taylor, T.S. Chang, "Application of Enzyme-Linked Immunosorbent Assay for Detecting Antibody to *Mycoplasma gallisepticum* Infections in Poultry," *Avian Diseases*, Vol. 27, No. 1, pp. 21–35, January–March 1983; and

H.M. Opitz, J.B. Duplessis, and M.J. Cyr, "Indirect Micro-Enzyme-Linked Immunosorbent Assay for the Detection of Antibodies to *Mycoplasma synoviae* and *M. gallisepticum*," *Avian Diseases*, Vol. 27, No. 3, pp. 773–786, July–September 1983; and

H.B. Ortmyer and R. Yamamoto, "Mycoplasma Meleagridis Antibody Detection by Enzyme-Linked Immunosorbent Assay (ELISA)," *Proceedings, 30th Western Poultry Disease Conference*, pp. 63–66, March 1981.

(5) The official molecular examination procedures for *M. gallisepticum* are the PCR test described in §147.30 of this subchapter and the real-time PCR test described in §147.31 of this subchapter. The official molecular examination procedure for *M. synoviae* is the PCR test described in §147.30 of this subchapter.

(c) [Reserved]

(d) *For avian influenza.* The official tests for avian influenza are described in paragraphs (d)(1) and (d)(2) of this section.

(1) *Antibody detection tests—(i) Enzyme-linked immunosorbent assay (ELISA).* ELISA must be conducted using test kits approved by the Department and the Official State Agency and must be conducted in accordance with the recommendations of the producer or manufacturer.

(ii) *The agar gel immunodiffusion (AGID) test.* (A) The AGID test must be conducted on all ELISA-positive samples.

(B) The AGID test must be conducted using reagents approved by the Department and the Official State Agency.

(C) The AGID test for avian influenza must be conducted in accordance with part 147 of this subchapter. The test can be conducted on egg yolk or blood samples. The AGID test is not recommended for use in waterfowl.

(D) Positive tests for the AGID must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

(2) *Agent detection tests.* Agent detection tests may be used to detect influenza A matrix gene or protein but not to determine hemagglutinin or neuraminidase subtypes. Samples for agent detection testing should be collected from naturally occurring flock mortality or clinically ill birds.

(i) *The real time reverse transcriptase/polymerase chain reaction (RRT-PCR) assay.* (A) The RRT-PCR tests must be conducted using reagents approved by the Department and the Official State Agency. The RRT-PCR must be conducted using the National Veterinary Services Laboratories (NVSL) official protocol for RRT-PCR and must be

conducted by personnel who have passed an NVSL proficiency test.

(B) Positive results from the RRT-PCR must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

(ii) *USDA-licensed type A influenza antigen capture immunoassay (ACIA).* (A) The USDA-licensed type A influenza ACIA must be conducted using test kits approved by the Department and the Official State Agency and must be conducted in accordance with the recommendations of the producer or manufacturer.

(B) Chicken and turkey flocks that test positive on the ACIA must be further tested using the RRT-PCR or virus isolation. Positive results from the RRT-PCR or virus isolation must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

(3) The official determination of a flock as positive for the H5 or H7 subtypes of avian influenza may be made only by NVSL.

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[36 FR 23112, Dec. 3, 1971]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §145.14, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§145.15 Diagnostic surveillance program for low pathogenic avian influenza.

(a) The Official State Agency must develop a diagnostic surveillance program for H5/H7 low pathogenic avian influenza for all poultry in the State. The exact provisions of the program are at the discretion of the States. The Service will use the standards in paragraph (b) of this section in assessing individual State plans for adequacy, including the specific provisions that the State developed. The standards should be used by States in developing those plans.